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PATENTS LAW, 5727-1967

בקשה לפטנט
Application for Patent

082/00665

אני, (שם המבקש, מענו – ולגבי גוף מאוגד – מקום התאגדותו)
I (Name and address of applicant, and, in case of body corporate-place of incorporation)

Sunlight Ultrasound Technologies Ltd.
Kiryat Weizman, Park Hamada, Bldg 3
P.O. Box 2513
Rehovot 76100

(An Israeli Company)

סנלייט אולטראסאונד טכנולוגיות בע"מ
קרית ויצמן, פארק המדה, בנין 3
ת.ד. 2513
רחובות 76100

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(בעברית) (Hebrew) קביעת מהירות עצם

(באנגלית) (English) BONE VELOCITY DETERMINATION

מבקש בזאת כי ינתן לי עליה פטנט
hereby apply for a patent to be granted to me in respect thereof.

* בקשת חלוקה – Application of Division	* בקשת פטנט מוסף – Application for Patent Addition	* דרישה דין קדימה Priority Claim		
מבקשת פטנט from Application	* לבקשה/לפטנט to Patent/Appl.	מספר/סימן Number/Mark	תאריך Date	מדינת האגוד Convention Country
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dated ____ מיום	dated ____ מיום			

* יפוי כח: כללי/מיוחד – רצוף בזה / עוד יוגש
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ת.ד 10256 פ"ת, 49002

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היום 8 בחודש נובמבר שנת 1998
This 8 of נובמבר of the year 1998

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קביעת מהירות עצם

BONE VELOCITY DETERMINATION

סנלייט אולטראסאונד טכנולוגיות בע"מ

Sunlight Ultrasound Technologies Ltd.
c:082/00665

BONE VELOCITY DETERMINATION

FIELD OF THE INVENTION

The present invention relates to non-invasive measurement of the mechanical properties of bone.

BACKGROUND OF THE INVENTION

It is known in the art that the velocity of a sound wave in a material depends on the mechanical properties of the material.

Bone velocity measurement typically uses one of two methods. In a first method, an ultrasound wave is transmitted across a bone, in a direction transverse to its axis, for example across the phalanx or across an ankle. In a second method, an ultrasonic wave is transmitted from a skin surface generally parallel to the bone, to the bone, and its reflections or emissions from the bone, at a distance along the axis of the bone, are detected.

In order to perform *in vivo* ultrasonic measurements of the mechanical properties of a bone, it is necessary to transmit an ultrasonic wave through the soft tissue surrounding the bone. Unfortunately, the thickness of the soft tissue varies along the length of the bone. Also, the soft tissue velocity is not a constant value for all soft tissues. These variations can affect the accuracy of the ultrasound propagation time measurement through the bone. Typically, the variations in thickness of the soft tissue and its velocity are either ignored or an attempt is made to cancel the effects of the soft tissue.

For example, U.S. Patent No. 5,143,072 and PCT publication WO 97/13145, the disclosures of which are incorporated herein by reference, describe method of overcoming the effects of the unknown thickness of the intervening soft tissue, by ensuring that the measurements are taken when the portion of the path which passes through soft tissue is of a same length for different measurements or by determining a soft tissue velocity.

U.S. Patent 4,819,753, the disclosure of which is incorporated herein by reference, describes a method of analyzing the status of a hip implant, by detecting the time of flight of vibrations from a hammer hitting the bone, at a knee and outside a spina iliaca posterior superior of a pelvis. In this method, very low frequency acoustic waves are generated and detected, between about 50Hz and 2kHz.

U.S. Patent 4,048,986, the disclosure of which is incorporated herein by reference, describes a method of diagnosing or identifying a person by measuring the effect on a polarization of an ultrasonic wave which travels between an elbow and a wrist or between a knee and an ankle. Audio-frequency waves appear to be suggested.

SUMMARY OF THE INVENTION

It is an object of some preferred embodiments of the invention to reduce uncertainties

in bone velocity determination caused by unknown thickness of overlying soft tissue.

An object of some preferred embodiments of the invention is to measure changes in mechanical properties of bones, especially in trabecular bone tissue.

One aspect of some preferred embodiments of the invention is that an ultrasonic wave for measuring bone velocity is transmitted through a joint between two bones. In a preferred embodiment of the invention, the wave is transmitted from the pelvis to a knee, thereby passing through the both a pelvic bone and a hip bone. Preferably a moderately high ultrasonic frequency is used, so that the wavelength is smaller than a cross-sectional diameter of a bone or at most two or three times its size, for example about 160kHz for a femoral neck. Theoretically, if the cross-sectional diameter is greater than about 0.7 time the wavelength, the velocity of the wave is about the same as if the cross-section was infinite. Also, the presence of small metal pins may have a negligible effect, for two possible reasons. First, if the diameter of the pin is small, the relatively low frequencies used will not be able to propagate through the pin. Additionally or alternatively, a complete reflection of waves from the pin is expected due to a usually large difference in acoustic attenuation between them, so there will be no effect on a shortest travel time.

An aspect of some preferred embodiments of the invention is that an acoustic velocity of the bone is measured along a main axis of a bone, preferably, along an entire bone. In a preferred embodiment of the invention, the bone is a femur. Preferably, the wave travels through the hip joint and measures the acoustic velocity along the femoral neck and/or a trochanter.

Another aspect of some preferred embodiments of the invention relates to substantially direct measurement of a trabecular portion of the bone, by ignoring and/or subtracting propagation time spent in a cortical portion. When measuring a long dimension of the bone, the percentage of travel through the cortical portion can be made relatively small as compared to travel through the trabecular portion. Additionally or alternatively, in certain configurations, two adjacent paths may have substantially the same cortical travel portions and different trabecular travel portions, so a difference between travel time along the two paths is expected to be mainly due to the trabecular bone. By subtracting the path lengths and dividing by the difference in time of flight, a trabecular velocity is preferably determined.

There is thus provided in accordance with a preferred embodiment of the invention a method of determining an acoustic velocity in a bone, comprising:

transmitting, from a location adjacent a first in-vivo bone, an acoustic wave having a wavelength about the same or smaller than a cross-section of the bone, which cross-section is perpendicular to a main travel direction of said acoustic wave in said bone;

receiving said acoustic wave at a location adjacent a second in-vivo bone; and

determining mechanical properties of at least one of the first and second bones, from a travel time of said wave through said first and second bones and a joint connecting said bones. Preferably, the joint is articulated.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more clearly understood by reference to the following description of preferred embodiments thereof in conjunction with the figures, wherein identical structures, elements or parts which appear in more than one figure are labeled with the same or similar numeral in all the figures in which they appear, in which:

Figs. 1A, 1B and 1C illustrate a method of femoral measurement in accordance with a preferred embodiment of the invention;

Fig. 2 illustrates a spinal measurement, in accordance with a preferred embodiment of the invention;

Fig. 3 illustrates various points on a body at which bone velocity may be measured in accordance with a preferred embodiment of the invention; and

Fig. 4 is a schematic illustration of a method of determining an acoustic velocity in a bone, in accordance with a preferred embodiment of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Figs. 1A and 1B illustrate a femoral measurement in accordance with a preferred embodiment of the invention. A femur 10 is connected to a pelvis 12 at a hip joint 14 and to a calf at a knee joint 18. Hip 10 generally comprises a femoral neck 16, which is not collinear with the rest of hip 10, and is angled at a trochanter 20. Fig. 1B is a side view of Fig. 1A, with a dotted line indicating a general outline of soft tissue which covers the bones shown in Fig. 1A. In a preferred embodiment of the invention, ultrasonic transducers are located at places where the thickness of underlying soft tissue is minimal and/or has a small variation between subjects, for example, at knee 24 (transducer 30), at the trochanter 20 (transducer 32) in the back of pelvis 12 and/or at a pubic area 22 (a transducer 34). In another preferred embodiment of the invention ultrasonic transducers may be placed at the two opposite trochanters, 20 and 20', to determine a velocity between the two trochanters. In various preferred embodiments of the invention, the selection of which of the transducers are transmitters, which are receivers and which are both, is a product deign consideration. Generally, only a single transmitter and a single receiver are required to measure a time of flight between two points. Although only measurement along one direction is generally necessary, in some cases, measurements in two directions may also be taken. Also, in some cases, measurement in one direction may be better (e.g., lower noise) than a measurement in the other direction.

Fig. 1C is a cross-sectional illustration of the pelvic area, showing a path which may be taken by an ultrasonic beam which travels between a location A and a location B (locations shown also in Fig. 3).

In a preferred embodiment of the invention, a time of flight of an ultrasonic wave is measured between two of the above transducers, whereby a bone of interest lies along a path taken by the ultrasonic wave. Preferably, the path includes hip joint 14. Alternatively or additionally, only a path in the pelvis is measured, for example between the pubic area 22 and location B or between location B and its mirror location on the other side of the pelvis. Alternatively or additionally, the path includes all of pelvis 12, for example by placing transducer 32 at a location "B" on the side of the pelvis opposite location A. Alternatively or additionally, the path includes both femurs, for example by measuring between a knee 26 (Fig. 1A) and knee 18. Alternatively or additionally, a transmitter (or a receiver) is placed at location 34 in order to measure times for both hips (for waves to or from transducers at knee 18 and knee 26).

In a preferred embodiment of the invention, an additional receiver and/or transmitter may be placed at one or more locations along femur 10, to determine times of flight to a middle of the femur.

It should be appreciated that the path of the ultrasonic wave in the bone is not straight, as the bone itself is not straight. Also, the fastest path along the bone may not be the shortest one.

The wavelength of acoustic waves is equal to the speed of sound divided by their frequency. For a given speed of sound, which is the property of the material through which the waves travel, the higher the frequency the smaller the wavelength. However, acoustic waves are attenuated along their travel, and higher frequencies are usually attenuated more. In a preferred embodiment of the invention, the frequency used is an ultrasonic frequency, preferably above 20kHz, more preferably between 100kHz and 200kHz, or even over 400kHz. In a preferred embodiment of the invention, the frequency is selected responsive to the bone being measured. Preferably, the frequency is selected to be low enough so that the attenuation by the travel through the bone, soft tissue and/or through the joint are not too high relative to a noise level of the measurement system. Alternatively or additionally, the frequency is selected to be high enough so that the wavelength is small compared to the sectional diameter of the bone, such that the wave travels substantially only through the bone and not through the soft tissue surrounding it. In a preferred embodiment of the invention, the frequency is such that the bone cross-section (preferably at the middle of the bone and/or its average) is approximately the same as the wavelength or at least within a factor of 2 or 3. Alternatively,

the wavelength is significantly smaller than the bone cross section.

It should be appreciated that in some preferred embodiments of the invention most of the travel time is in the bone and not in the soft tissue, so the travel time in the soft tissue has a small effect on the total travel time. Preferably, the soft tissue (thickness) is ignored in the measurement. Alternatively or additionally, the soft tissue thickness is measured, for example by acoustic imaging or by measuring a time of flight for a reflection from the bone, and the travel time is subtracted. Alternatively or additionally, a soft tissue velocity is estimated, for example, to be about 1500 m/s.

In a preferred embodiment of the invention, the travel time is mostly dependent on the slow bone portions, i.e., those bone portions with the lowest strength, which portions are often the bone portions of interest.

In a preferred embodiment of the invention, the time of flight is measured by determining the first arriving acoustic wave. Alternatively, the time of flight is determined by correlating a received wave with the transmitted wave. Or by correlating two received waves (for example at two knees).

Alternatively or additionally to measuring a time of flight, changes in polarization of the transmitted wave may also be measured. Alternatively or additionally, a frequency dispersion effect of the bone travel on the wave may be measured. Alternatively or additionally, a frequency transfer function (power spectrum) and/or attenuation function may be measured.

In a preferred embodiment of the invention, the transmitted wave is a pulsed wave, for example having a duty cycle of less than 30%, 20%, or 10%. Alternatively, the wave is a continuous or near continuous wave. Preferably, the wave comprises a narrow-band-frequency wave, for example having a bandwidth of less than 60%, 40% or 30% of its center frequency. Alternatively or additionally, a wide-band-frequency wave is used, for example having a bandwidth of more than 80%, 100% or 120% of its center frequency. Alternatively or additionally, a temporal envelope, having frequency and/or amplitude characteristics, with a temporal length of more than one wavelength is overlaid on the wave.

In one example, a 2 microsecond pulse having a center frequency of 160kHz is used, this yields a bandwidth of about 500kHz.

In a preferred embodiment of the invention, the wave is transmitted into the bone at an angle substantially normal to the bone surface, to increase the efficiency of the transmission of the wave and/or to reduce the effects of overlying tissue. Alternatively or additionally, the wave is transmitted in a direction parallel to the bone's long axis. A combination of the two preferred transmission methods often dictates that the wave be transmitted at a joint, usually

when the joint is bent.

An apparatus in accordance with a preferred embodiment of the invention preferably comprises a transmitter and a receiver mounted on a "U" shaped frame. Alternatively, at least one of the ultrasonic elements may be mounted on a curved segment attached to the frame, to better fit around a leg or a pelvis. In a preferred embodiment of the invention, at least one of the transducers is movable along the base of the frame and fastenable in place. In use, the transmitters are preferably located at the desirable locations and then fastened in place. The measurements are taken, preferably by sampling directly into a computer. The distance between the transmitters is preferably measured off the frame, preferably automatically, for example using methods known in the art (e.g., optical or linear encoders). Alternatively or additionally, the distance is determined by measuring a time of flight between the transmitter and the receiver in the material of the frame (which has a known velocity) or in the air (which has a known velocity). Alternatively, a fixed frame is used, having a know distance between the transducers. In a preferred embodiment of the invention, at least one of the transducers is mounted to a bed, on which a patient may lie and/or to which the patient may be fastened.

It should be appreciated that the travel time in the frame is generally much shorter than the travel time in the bone so the frame travel time does not usually interfere with detecting the wave which travels through the bone. Alternatively or additionally, the ultrasonic elements are mounted onto the frame using dampers which absorb ultrasonic waves, so substantially no waves will travels through the frame.

Alternatively or additionally, an apparatus may comprise independent transducers which include position sensors mounted thereon, Thus, their relative positions may be measured relative to a base station and/or directly relative to each other. Preferably RF position or distance measurement is used. Alternatively or additionally, airborne ultrasonic position and/or distance sensing is used, possibly using the same transducers.

Alternatively, the distance between the transducers is not determined a-priori.

In a preferred embodiment of the invention, the time of flight measurements are used for comparison studies, for example, between patients, preferably using a table of expected values; between multiple measurements of a single patient over time, preferably utilizing tattoo markings on the patient to mark the locations at which transducers are placed; and/or between opposing limbs of a same patient. As can be appreciated, in some of these cases, it is not necessary to know an exact speed of sound. Rather, it is enough to detect a change (absolute and/or relative) in a time of flight.

In a preferred embodiment of the invention, the measurements of time of flight are used in a group comparison method. For example, for each age group/disease stage, one or

more typical velocity ranges are determined. When a patient is tested, the determined velocity is compared to the range expected in the age group/disease stage. A "T" score may be defined, to describe the relationship, with, for example, T=(measured velocity - average velocity in "fastest" age group)/(standard deviation of velocity in the "fastest" age group). Typically, the fastest age group is between 30 and 34. The units of the "T" score are standard deviation units and are usually negative, especially for diseased bone.

Fig. 2 illustrates a spinal measurement, in accordance with a preferred embodiment of the invention. A patient 40 generally has a spine 42, with two special areas of interest usually being defined, a lumbar region 46 and a cervical region 44. In a preferred embodiment of the invention, the time of flight is measured between two vertebra, for example a vertebra 48 and a vertebra 52 in lumbar region 46. Alternatively or additionally, the time of flight in a single vertebra may be measured. Alternatively or additionally, the time of flight along a significant portion of spine 42, for example half of the spine, may be measured.

It should be noted that depending on the frequency used, several paths are possible between two adjacent vertebra. In a first path, the ultrasonic wave travels between the spines of the vertebra, bridging a considerable amount of soft tissue. In a second path, the wave travels through the main part of the backbone, through the spinal disks. A third possible path is along soft tissues that surround the spine. The first and second paths are differentiated by two features of the paths. One feature is that the amount of soft tissue in the second path is smaller than in the first path. Another feature is that the dimensions of the vertebra are larger in the second path than in the first. In a preferred embodiment of the invention, the two paths may be chosen between by appropriately selecting an ultrasonic frequency. A low frequency will not be able to travel as fast in the bone portion of the first path as in the bone portion of the second path. In a preferred embodiment of the invention, a high enough frequency is used, for example 40 kHz, so that the third, soft tissue path, is slower than at least one of the other two paths. Preferably, a time of arrival window mechanism is used to differentiate between the travel along the two paths. Such a relatively low frequency may also be required to overcome the high attenuation caused by the existence of an extra joint for every additional vertebra measured.

In a preferred embodiment of the invention, the travel times may be compared between groups of vertebrae, for example between (L1-L5) and (T1-T12). Preferably the groups comprises same types of vertebrae. Alternatively or additionally, the groups are of lengths of approximately integer multiples, so a velocity per vertebra may be calculated and/or compared between the groups (e.g., by diving the time of flight of one group by that of the other group). Alternatively or additionally, the groups comprise same numbers of vertebrae. Alternatively or

additionally, the groups include one or more common vertebrae.

In a preferred embodiment of the invention, the measurements may be used to detect spinal fractures, for example, compression fractures and/or cervical spine injuries, by detecting changes in velocity, waveform polarization, power spectrum, and/or other parameters of the acoustic wave. In a preferred embodiment of the invention, a determination of spinal fractures, especially of cervical spine injuries, may be performed at a site of an automobile accident, to decide on movement options.

In a preferred embodiment of the invention, the above methods of travel time determination and/or acoustic velocity determination (by dividing distance by travel time) may be applied to other bones of the body, for example, the arms, wrists, fingers, shoulders, collar bone, shin and/or jawbone. Mechanical characteristics of the bone may also be assessed from the time of flight measurements, using methods known in the art, for example, as in the above referenced patents and publications.

Preferably, the measurement is made between points where the underlying soft tissue is thinnest. Preferably, the measuring points are at or near ends of the bone. Alternatively or additionally, at least one of the measuring points is at a middle of a bone. Preferably, only two bones (and one joint) are measured. Alternatively, two, three or more joints may be measured, for example, entire fingers, or the spine mentioned above. In some preferred embodiments of the invention, not all the joints are articulated joints, for example, cartilage joints, such as rib joints or wrist joints and/or knitted joints such as in the skull.

In a preferred embodiment of the invention, such measurements are used to detect onset, progression and/or regression of osteoporosis. Alternatively or additionally, the measurements may be used to monitor a fracture healing process.

In a preferred embodiment of the invention, such measurements may be used for identification purposes, for example, by storing relative travel times along each of five fingers of a right hand. Even if bone loss occurs it may be expected to be similar for all the fingers.

Fig. 3 illustrates various points on a body at which bone velocity may be measured in accordance with a preferred embodiment of the invention. The points are indicated with a letter, such as locations A and B described above with reference to Fig. 1C.

In an experiment, a frequency of 150kHz was used to measure velocities between points A and B in healthy patients. The velocity measured was between 1800 and 1900 m/s. the thickness of soft tissue underlying locations A and B is about 1 and 1.5 cm respectively. In a preferred embodiment of the invention, the soft tissue velocity and/or travel time is estimated, to yield a more exact bone velocity. One way of estimating the soft tissue velocity is to assume the bone velocity is about 1800 m/s and to determine the soft tissue velocity from

the soft tissue thickness. The soft tissue thickness may be determined, for example, by measuring reflection from an underlying bone or using methods described in PCT publication WO 97/13145, the disclosure of which is incorporated herein by reference.

Another set of locations comprises a location F at an elbow and a location E at a hand. In a preferred embodiment of the invention, the location E is a knuckle, so that when a fist is made, the ultrasonic wave enters the bone at a normal angle. The knuckle is preferably used instead of the finger tip, to avoid any interaction with- and/or reflections caused by- a fingernail. In an experiment on healthy subjects using a frequency of 150kHz, velocities between 2600 and 2900 m/s were measured. The soft tissue effect is preferably ignored, since the soft tissue is very thin at points E and F (relative to length of path in the path in the bone).

Another set of locations comprises a location I and a location J at two opposing shoulders. Alternatively or additionally, one of the locations may be at the back of a neck. Another set of locations comprises a location G at a large toe and a location H at a base of an ankle. In an experiment in health subjects, a frequency of 150kHz yielded velocities of about 1900-2000 m/s.

Fig. 4 is a schematic illustration of a method of determining an acoustic velocity in a trabecular portion 144 of a bone 140, in accordance with a preferred embodiment of the invention. A transducer 146 is shown at one side of bone 140 and a pair of transducers 148 and 150 are shown at spaced away locations. It is noted that transducer 146 is substantially perpendicular to transducers 148 and 150. Ignoring intervening soft tissue, a path from transducer 146 to transducer 148 (or transducer 150) includes a short segment "a" in a cortical bone portion 142 and a long segment "b" (or "c") in trabecular bone portion 144. A third short segment "d" ("e") in the cortical bone completes the path. The frequency of the wave is preferably selected so that travel of the wave only through cortical bone is substantially attenuated, due to the small cross-section of the cortical bone. If a distance between transducer 146 and transducer 148 is relatively long compared to the distance between transducer 148 and transducer 150, paths "b" and "c" will substantially overlap and have only a small angle α between them. Path section "a" will generally be the same segment for both paths. Additionally, if transducers 148 and 150 are close together, paths "d" and "e" will pass through substantially the same thickness and/or type of cortical bone. If angle α is small, the difference in path lengths is substantially equal to the distance between transducers 148 and 150. The time of flight in trabecular bone 144 may be determined by subtracting the times of flight for the two paths. The velocity may be determined by diving the distance between the two transducers by the subtracted time of flight. Alternatively or additionally, to using two transducers, a single transducer may be moved between locations 148 and 150 and/or further

locations along the bone axis. In a preferred embodiment of the invention, a horizontal distance "h" between transducer 146 and transducer 148 is made large enough so that the fastest wave does not travel only along the cortical potion of the bone.

In a preferred embodiment of the invention, the contribution of soft tissue travel time to the total travel time may be ignored for the same reasons as the effect of cortical bone because similar thickness and velocities of the soft tissue are involved for the two paths. Also, the total thickness of the soft tissue (and cortical bone) may be selected to be small relative to the trabecular bone path.

The measurement of Fig. 4 may be applied at an ankle, with transducers 146 being at a base of the ankle and transducers 148 and 150 being along the side of the ankle bone. Alternatively or additionally, transducers 148 and 150 may be further down the foot, so that the waves travels through multiple bones. Alternatively or additionally, the measurement may be performed between an elbow and points further down the arm, near the wrist. Alternatively or additionally, these measurements may be performed at other points in the body where there is a significant distance between transducers 146 and 148.

In a preferred embodiment of the invention, the ultrasonic bone velocity measurement may be restricted to substantially a joint area, for example, from just above an elbow to just below an elbow. In a preferred embodiment of the invention, the measurement apparatus comprises a "V" shaped apparatus with a transducer at an end of each arm of the "V: and with a variable base angle. Alternatively, a "U" shaped apparatus, as described above, may be used. Alternatively or additionally, a grid type probe is used for velocity measurements in bone and/or joints, in which individually excitable (and/or receiving) portions are available on a flexible or a rigid substrate.

In a preferred embodiment of the invention, such bone and/or joint velocity measurements are performed at multiple joint positions. Preferably, these multiple measurements are used since the path may be expected to include different parts of the bone, depending on the joint angle. Alternatively or additionally, the multiple measurements accommodate different thicknesses of joint tissue between the bones.

The present invention has been described in terms of preferred, non-limiting embodiments thereof. It should be understood that features described with respect to one embodiment may be used with other embodiments and that not all embodiments of the invention have all of the features shown in a particular figure. In particular, the scope of the invention is not defined by the preferred embodiments but by the following claims. Section titles, where they appear are not to be construed in limiting subject matter described therein, rather section titles are meant only as an aid in browsing this specification. When used in the

following claims, the terms "comprises", "comprising", "includes", "including" or the like means "including but not limited to".

CLAIMS

1. A method of determining an acoustic velocity in a bone, comprising:

transmitting, from a location adjacent a first in-vivo bone, an acoustic wave having a wavelength about the same or smaller than a cross-section of the bone, which cross-section is perpendicular to a main travel direction of said acoustic wave in said bone;

receiving said acoustic wave at a location adjacent a second in-vivo bone; and

determining mechanical properties of at least one of the first and second bones, from a travel time of said wave through said first and second bones and a joint connecting said bones.

2. A method according to claim 1, wherein the joint is articulated.

For the applicant,

Fenster & Co. Patent Attorneys
c:082/00665

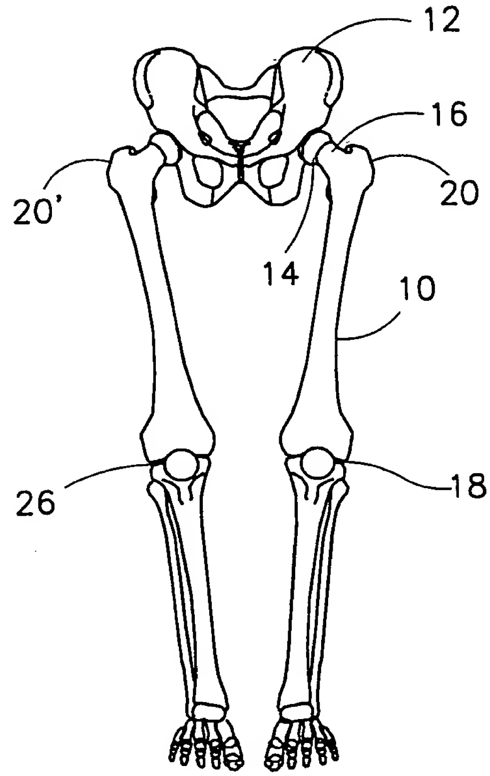

FIG.1A

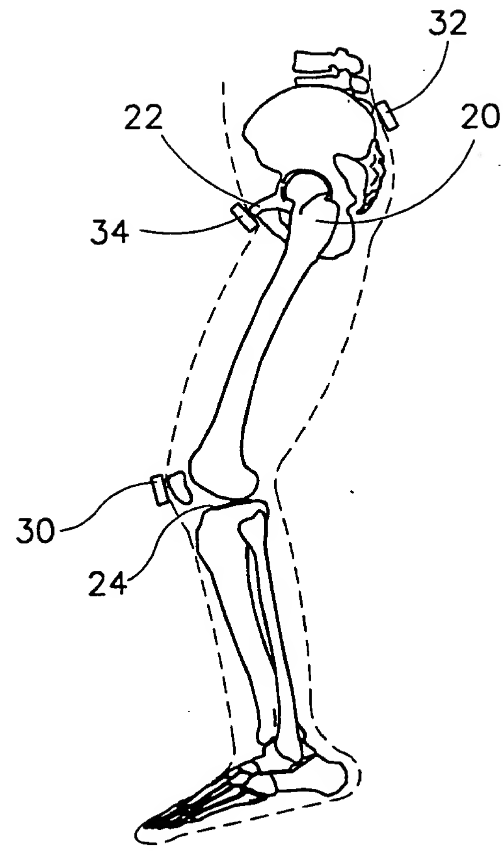

FIG.1B

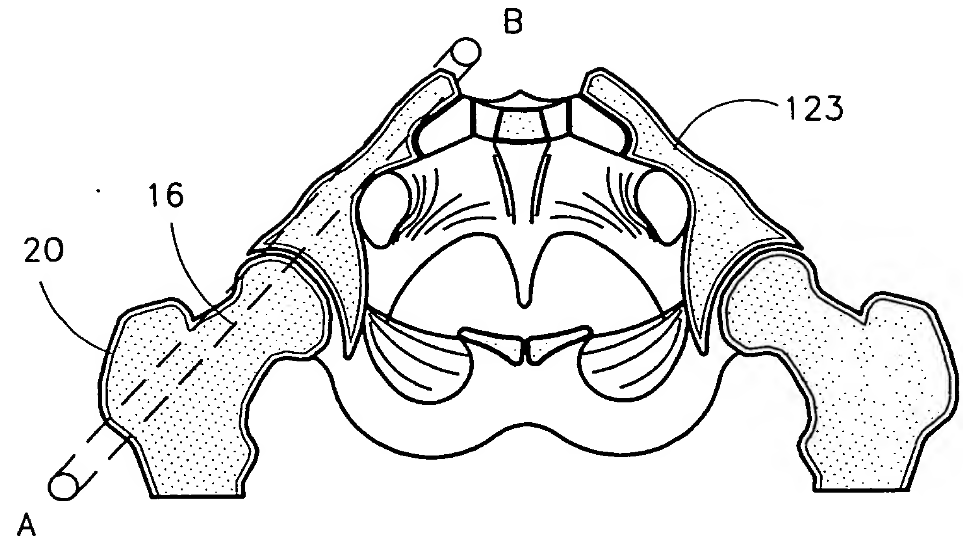

FIG.1C

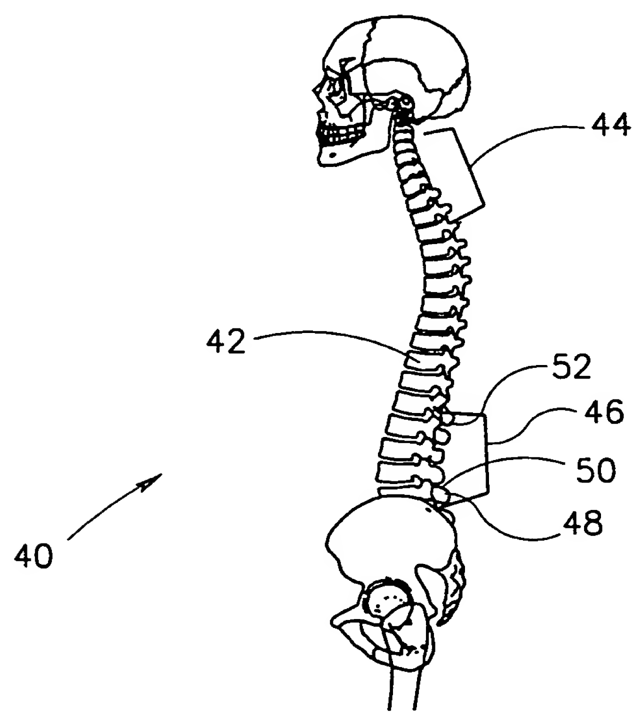

FIG.2

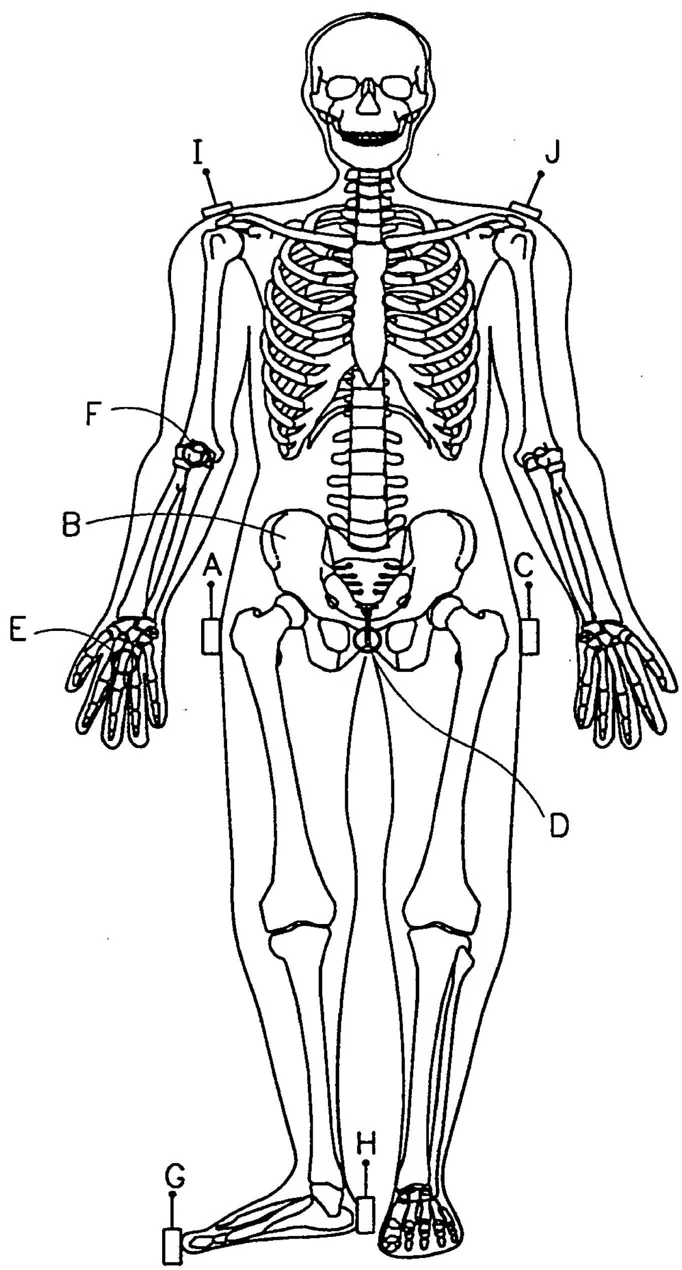

FIG.3

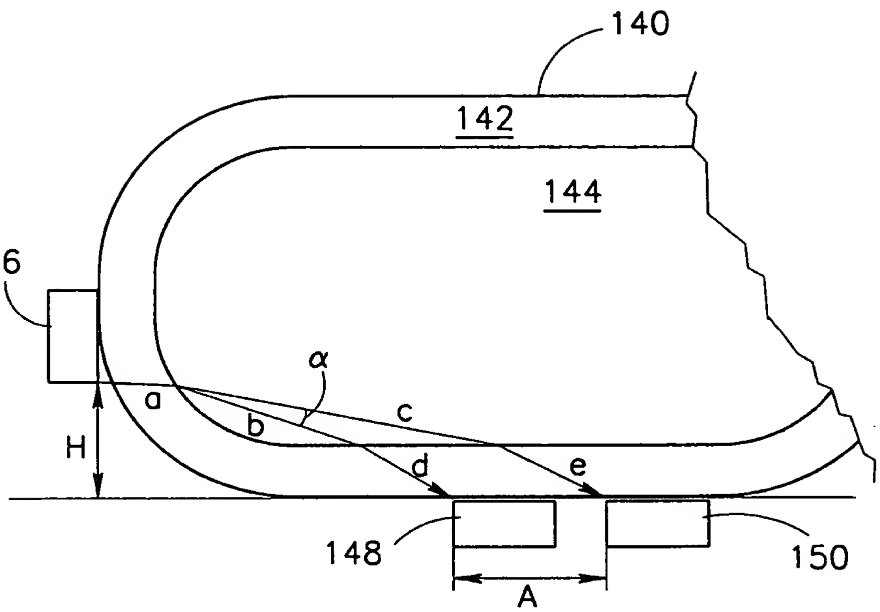

FIG.4